

***Remarks***

Upon entry of the foregoing amendment, claims 1-11 are pending in the application, with claim 1 being the independent claim. Claim 1 is sought to be amended. Support for the amendment to claim 1 may be found, e.g., in paragraph [0073] of the published application. No new matter has been added by this amendment and its entry is respectfully requested. Entry of the amendment is believed proper as the amendment is accompanied by a Request for Continued Examination.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***Obviousness-type Double Patenting Rejections***

The Examiner rejected claims 1-11 for obviousness-type double patenting, over claims 16-30 of U.S. Patent No. 5,780,055 (“Habib”), in view of U.S. Patent No. 4,910,023 (“Botzolakis”). Applicants respectfully traverse this rejection.

Solely to advance prosecution, and not in acquiescence to the Examiner’s rejection, Applicants have amended claim 1 to require that the active-loaded particles exhibit substantially no fracturing or degradation. The dosage form of claim 1 comprises an active cushioning component which is a bead, granule, particle or pellet comprising an active-loaded particle core surrounded by a porous cushioning layer. The active cushioning component is made by a process comprising admixing the core and cushioning components followed by freeze-drying.

Claim 16 of the '055 patent recites a tablet comprising, *inter alia*, two separate beads, *viz.*, biologically active beads and cushioning beads, wherein the cushioning beads are prepared by extrusion-spheronization and freeze-drying.

Applicants respectfully submit, based on the reasons below under ***“Rejections under 35 U.S.C. § 103,”*** that claims 1-11 are nonobvious over the dosage form embodied in claims 16-30 of Habib in view of Botzolakis.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

***Rejections under 35 U.S.C. § 103***

The Examiner rejected claims 1-11 under 35 U.S.C. § 103(a) as allegedly obvious over Habib (U.S. Pat. No. 5,780,055) in view of Botzolakis (U.S. Pat. No. 4,910,023).

The Examiner's original rejection, as stated in a prior Office Action, is below:

Obviousness stems from the art's recognition that drugs are conveniently released from particles made from the same excipients as those in Habib's cushioning particles (microcrystalline cellulose and disintegrant). Thus the claims represent no more than a rearrangement of components known in the art to be useable together, wherein each component performs its predictable, art recognized function. The use of cushioning beads is known in Habib, and the use of drugs in beads with the same excipients as the cushioning beads is known in Botzolakis. The cushioning component, in the instant invention, still serves its art-recognized functions of cushioning for improved tablet hardness and releasing a drug; the art recognizes these as properties of the claimed excipients. The artisan would thus enjoy a reasonable expectation of success, because the combination or rearrangement of components is expected to perform (and indeed does perform) the same functions as the components separately.

*Office Action* dated April 18, 2008.

In the Final Office Action, in response to Applicants' arguments, the Examiner contends that Habib does "not teach away from any aspect of Botzolakis that is relevant to the claims at issue" and that "Habib does not teach away from Botzolakis as a whole, but rather offers an improvement over Botzolakis's granulation methods." Office Action dated December 18, 2009, page 4. The Examiner further contends that Habib teaches that lyophilization produces the best results, and that a person skilled in the art would freeze-dry Botzolakis's particles. *Id.*, p. 5. Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's analysis of the cited art and respectfully assert that the Examiner has not established a *prima facie* case of obviousness. Specifically, Applicants respectfully assert that a person skilled in the art would not combine Habib and Botzolakis in the manner claimed by the Examiner. Furthermore, Applicants assert that Habib teaches away from their combination and any expectation of achieving success. Applicants respectfully assert that the differences between Habib, individually, and in combination with Botzolakis, and the claimed invention are substantial and require much more than a mere "rearrangement" of the components of Habib and Botzolakis.

Habib teaches freeze-drying cushioning beads separately and combining them with active ingredient-loaded beads that have not been freeze-dried. While Habib teaches that freeze-dried beads when combined with active ingredient-loaded beads provides adequate cushioning of the active ingredient-loaded beads, this does not provide a reason, let alone an expectation of achieving success, to freeze-dry the beads of Botzolakis. It is a leap to conclude that it would be obvious to freeze-dry the Botzolakis particles and achieve the same results as achieved by Habib.

Importantly, Habib teaches that the inert cushioning beads should be mechanically weaker than the active ingredient-loaded beads, and deform at lower pressures to prevent fracture of the active ingredient-loaded beads. Habib creates the mechanically weaker beads by freeze-drying the cushioning beads, which produces highly porous and compactable beads - since the removal of water in the frozen state leaves a skeleton of solid material. *See* Habib at col. 46, lines 7-8; col. 30, lines 20-30; col. 21, lines 58-60, and col. 50, lines 42-46. Applicants respectfully submit that Habib, at least implicitly, if not expressly, *teaches away* from freeze-drying the cushioning beads together with the active-loaded particles, because to do so would ostensibly frustrate Habib's goal of creating *differences* in the mechanical strength of the cushioning beads and ingredient-loaded beads. If a proposed modification renders a prior art invention being modified unsatisfactory for its intended purpose, *then there is no suggestion or motivation to make the proposed modification. See, e.g., In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Thus, Applicants respectfully assert that the Examiner's proposed modification of Habib could jeopardize the goal of Habib, *viz.*, to create differences in the mechanical strength of the beads, and therefore, one skilled in the art would not combine the cited art in the manner described by the Examiner. Moreover, if the cushioning beads and the ingredient loaded-beads are both freeze-dried together, Applicants respectfully assert that a person skilled in the art would have no reasonable expectation of success that the cushioning layer would be mechanically weaker than the active-loaded core to the extent required to provide an adequate cushioning effect and prevent fracturing or degradation of the active-loaded particles as required by amended claim 1. Thus, Applicants respectfully assert that the

combination of Habib and Botzolakis do not render Applicants' claimed invention *prima facie* obvious.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

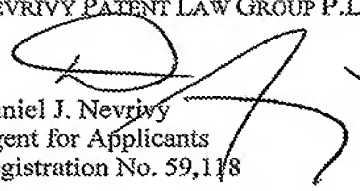
### ***Conclusion***

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Date: March 18, 2010

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